

REMARKS

Claims 28, 31-38 and 46-49 are pending. Applicants canceled claims 47-49 without prejudice to the subject matter contained therein. Applicants amended claims 28, 31, 33 and 34. The specification (see, for example, pages 2 to 8 and Examples in pages 30 to 78) provides support for the amendments. Applicants added new claim 50 and it finds support in original filed claims. No new matter has been introduced by the instant amendments.

35 U.S.C. §112, first paragraph

Claims 28, 31-37 and 46-49 stand rejected under 35 U.S.C. §112, first paragraph as allegedly having a non-enabling specification. The Examiner asserts that the specification, while being enabling for a compound, composition, pharmaceutically acceptable salt thereof, where R_{1a} is an aryl group, does not reasonably provide enablement for a compound, composition, or pharmaceutically acceptable salt where R_{1a} can be a monocyclic or bicyclic heteroaryl. Applicants respectfully disagree for at least the following reason.

Applicants respectfully note that, "[f]or a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." MPEP 2164.02

Applicants amended claim 28 so that R_{1a} is a monocyclic heteroaryl which the applicant asserts is reasonably enabled by actual examples in the application. The claimed genus is supported by the general method of production of compounds applicable to the genus as a whole. Example 17 describes the synthesis of compounds in which R_{1a} (referred to as R' in the specific example 17) is monocyclic heteroaryl such as thienyl.

Applicants note that, "[t]he scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required." MPEP 2164.03.

Therefore, based on this disclosure of representative examples, one of skill in the art would expect that the claimed genus of compounds could be made and used in the same manner as the representative examples without undue experimentation.

Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection.

Claim 48

Claims 48 stands rejected under 35 U.S.C. 112, first paragraph, as allegedly having a non-enabling specification. The Examiner asserts that the specification does not reasonably provide enablement for any other compositions combined with "anti-obesity agent, anti-hypertensive agent, inotropic agent or a hypolipidemic agent." Applicants respectfully traverse this assertion; however to expedite prosecution of the present invention, Applicants canceled claim 48 without prejudice to the subject matter contained therein. Applicants reserve the right to pursue the subject matter of claim 48 in a Continuation application.

35 U.S.C. §112, Second Paragraph

Claims 28, 31-37 and 46-49 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. The Examiner asserts the terms "heteroaryl" or "heterocyclyl" to be vague and indefinite. Applicants respectfully disagree.

The terms in question are described in the specification on pages 6 to 8. "Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph." See MPEP 2173.04. However, to expedite prosecution, all "heteroaryl" and "heterocyclyl" terms have been replaced with "monocyclic heteroaryl" or "monocyclic heterocyclyl". Pages 6 and 8 of the specification provides support for the amendment.

Claims 28, 31-37 and 46-49 also stands rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite due to the term "optionally substituted." Applicants respectfully disagree with the assertion that "optionally substituted" is *per se* indefinite. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. See MPEP 2173.05(b).

To expedite prosecution Applicants amended claims 28 and 33 to replace "optionally substituted" term for aryl, alkyl, cycloalkyl, heterocyclyl and heteroaryl by a specific group of

substituents. Support to the amendments can be found for example in pages 2 to 8 and in numerous examples 1 to 93.

Applicants have left "optionally substituted amino" in the claims because it is clearly defined in the specification on page 4 or 5.

Applicants canceled claims 47 and 49 without prejudice to the subject matter contained therein. The cancellation renders the §112, 2nd rejection moot.

Allowable Subject Matter

Applicants acknowledge and thank the Examiner for indicating allowable subject matter.

Conclusion

Applicants have addressed each and every issue set forth by the Examiner. Applicants respectfully submit that the present application is in good condition for allowance.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (617) 871-4125.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 50-4409 for any additional fees under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17; particularly extension of time fees.

Respectfully submitted,

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